

OCT 29 2004

Denka Seiken Co., Ltd.  
Pre-market Notification  
HDL-EX SEIKEN Assay Kit

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**I. 510(k) Summary**

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is: K041090

(A)(1) Submitter's name: Denka Seiken Co., Ltd.

Submitter's address: 3-4-2, Nihonbashi kayabacho,  
Chuo-ku  
Tokyo, Japan 103-0025

Submitter's pilot telephone number: +81-3- 3669-9421

Contact Person: Mr. Toshimi Matsunaga  
Manager  
Pharmaceutical Affairs

Contact Person's telephone number: +81-250- 42-7222

Date Summary Prepared: October 1, 2004

(2) Trade or proprietary device name: HDL-EX SEIKEN Assay Kit

Common or usual name: Homogeneous assay for high density lipoprotein cholesterol

Classification Name: High density lipoprotein cholesterol test

Panel: Clinical Chemistry

Class: I

Product Code: LBS

(3) Legally marketed predicate device: Ultra N-Geneous HDL Cholesterol Reagent  
[Genzyme Corp.] (K021316)

(4) Subject device description:

The HDL-EX SEIKEN Assay Kit is an *in vitro* diagnostic test for the quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum and heparinized- or EDTA-plasma on automated chemistry analyzers. The HDL-EX SEIKEN Assay is a homogeneous method for directly measuring HDL-C levels in serum and plasma without the need for any off-line pretreatment or centrifugation steps.

(5) Subject device intended use:

The HDL-EX SEIKEN Assay Kit is an *in vitro* diagnostic test for the quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum and heparinized- or EDTA-plasma on automated chemistry analyzers.

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(6) Performance data:

The HDL-EX SEIKEN Assay and the predicate device, Ultra N-Geneous HDL Cholesterol Reagent [Genzyme Corp.] have only relatively minor differences in that the differences do not affect the performance, safety or effectiveness of the measurement.

Comparative performance studies, when conducted on 150 donor samples, yielded a high correlation coefficient upon comparison of the HDL-EX SEIKEN Assay and the Ultra N-Geneous HDL Cholesterol Reagent. The correlation coefficient  $r = 0.991$ ; slope = 1.041, y intercept = 0.015.

Precision studies were conducted using the HDL-EX SEIKEN Assay Kit. Within run and between day studies were performed using three levels of control material for each. In both studies, the HDL-EX SEIKEN Assay showed very similar CVs as shown in the kit insert of the predicate device.

These findings serve to demonstrate that the performance of the HDL-EX SEIKEN Assay Kit is substantially equivalent to the predicate device, Ultra N-Geneous HDL Cholesterol Reagent [Genzyme Corp.].



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 29 2004

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Toshimi Matsunaga  
Manager of Regulatory & Pharmaceutical Affairs  
Denka Seiken Co., Ltd.  
1-2-2 Minamihoncho  
Gosen City  
Niigata,  
Japan 959-1695

Re: k041090  
Trade/Device Name: HDL-EX SEIKEN Assay Kit  
Regulation Number: 21 CFR 862.1475  
Regulation Name: Lipoprotein test system  
Regulatory Class: Class I  
Product Code: LBS  
Dated: October 1, 2004  
Received: October 4, 2004

Dear Ms. Matsunaga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

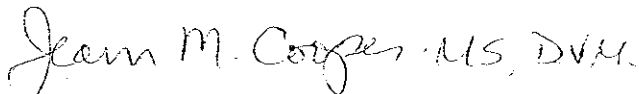
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Jean M. Cooper MS, D.V.M.".

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

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**C. Indications for use**

510(k) Number (if known): K041090

Device Name: HDL-EX SEIKEN Assay Kit

**Indications For Use:**

The HDL-EX SEIKEN Assay Kit is an *in vitro* diagnostic test for the quantitative determination of high-density lipoprotein cholesterol (HDL-C) in human serum and heparinized- or EDTA-plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus, atherosclerosis and various liver and renal diseases). The device is intended to be used on automated chemistry analyzers in clinical laboratories.

Prescription Use   X   AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k)   K041090